

patents, prices and access to

medicines

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Who we are

ActionAid International's vision is a world without poverty in which every person can exercise their right to a life of dignity. We currently work with nine million people in 40 countries across Africa, Asia, Latin America and the Caribbean to obtain this goal.

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“The single most important step we must now take is to provide access to treatment throughout the developing world. There is no excuse for delay. We must start now. If we discard the people who are dying from AIDS, then we can no longer call ourselves decent people.”

Nelson Mandela¹

At least six million people are in desperate need of medicines to treat HIV/AIDS and related infections, including TB and malaria. Without such treatment they will die. Generic versions of these medicines are being produced at low prices in developing countries such as Thailand, India, Brazil and South Africa but in order to protect their powerful pharmaceutical companies, industrialised nations are making it increasingly difficult for poor countries to import them.

International patenting rights on medicines are being protected by World Trade Organisation's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)² as well as by the numerous bilateral and regional trade agreements between developed and developing countries.

ActionAid International, like many poverty and rights focused organisations, is concerned about the way that intellectual property rights (patents) can stifle development. It is not alone in these concerns. The UK Commission on Intellectual Property Rights and Development Policy has questioned whether a global norm for patent protection is in the best interests of developing countries and whether an individual or company should be able to take out a patent on products that have important societal implications.³

Patent protection can increase prices⁴ and put drugs out of reach for poor people as well as for developing country governments seeking to provide antiretroviral medicines as part of the World Health Organisation's 3 by 5 initiative.

Patents and research

Research by the UK Commission's on Intellectual Property Rights and Development Policy revealed that less than 5% of pharmaceutical research budgets is spent on diseases predominantly affecting developing countries.⁵ Thus between 1975 and 1999, only thirteen of the 1,395 drugs developed were specifically indicated for tropical diseases.⁶ The fact is that pharmaceutical research by private companies is driven by the need for profit and thus focuses on markets in rich industrialised countries, rather than on the needs of poor people in developing countries.

This is illustrated by the different responses to HIV/AIDS, tuberculosis (TB) and malaria. Because HIV/AIDS is common to both rich and poor countries it has been the subject of considerable private sector research. In contrast, TB and malaria, diseases most prevalent in developing countries, have received little attention. This despite the fact that TB is the leading cause of death among HIV-infected people in developing countries, and about one third of them are co-infected with TB.⁷

¹ Speech at the International AIDS Society conference, 15 July 2003, Paris

² See also, ActionAid International, "Access to Medicines: Ensuring People's Rights", July 2003

³ Commission on Intellectual Property Rights, Integrating property rights and development policy, 2003, London. Full CIPR report available at www.iprcommission.org/graphic/documents/final_report.htm

⁴ WHO and UNAIDS, Treating 3 million by 2005: Making it happen, The WHO Strategy, 2003, Geneva

⁵ Commission on Intellectual Property Rights, 2003, *ibid*

⁶ Trouiller, P. et al "Drug Development for Neglected Diseases: a Deficient Market and a Public Health Policy Failure", 2002, *The Lancet*, vol. 359, pp.2188 – 94. Source: <http://www.thelancet.com>

⁷ See UNAIDS "Report on the Global HIV/AIDS Epidemic 2002", 2002, Geneva

Patents and pricing

The price of medicines is a key factor in determining how accessible they are to poor people. The more they cost the less money is available for other essentials like food and shelter. Where prices make medicines unaffordable, as has been the case for ARVs, the result is ill health and death. Of course, markets, government regulations, tariffs, competition and purchasing power all impact on the price of drugs. However, comparative international

research has demonstrated that copies of drugs patented elsewhere are much cheaper in markets which do not offer patent protection. "The Indian market, where there is no product protection, is the lowest priced in the world. One of our studies indicated that for 12 drugs covering a range of conditions, US prices ranged from four to 56 times the price of equivalent formulations in India."⁸

Patent protection in the WTO

The WTO's multilateral rules on intellectual property rights give patent owners 20 years of protection for their 'inventions'. In effect, patent protection grants pharmaceutical companies a monopoly over products and allows prices to be set at levels consistent with the presence of minimal levels of competition.

As the disastrous impact of HIV/AIDS became apparent, developing countries stepped up their demands for a change in TRIPS rules to deal with the crisis. In response to their protests, the WTO's 2001 Doha Declaration reaffirmed the right of countries to use compulsory licensing⁹ to manufacture of drugs to address public health problems. However, manufacture was only permitted for domestic use.¹⁰ This did nothing to solve the problems faced by the world's poorest countries, the Least Developed Countries, because although they do not have to comply with TRIPS until 2016, most have no pharmaceutical manufacturing capacity. If they want cheap generic drugs these must be imported.

In 2003, in an effort to diffuse tensions immediately prior to the WTO Ministerial meeting in Cancun, WTO members agreed a waiver to the TRIPS Agreement which seemingly resolved the issue of giving poor countries access to essential medicines without breaching WTO intellectual property rights rules. This 'Decision' of the WTO General Council on 30th August 2003 is a temporary waiver and has yet to be agreed as a formal amendment to the TRIPS Agreement. In ActionAid International's view, the 'solution' contained in the waiver is no solution at all. It is very complex, ambiguous and cumbersome, involving twelve time-consuming steps¹¹ which must be fulfilled every time an export-import of generic drugs takes place. Even if importing governments are willing to struggle with the process, it is bound to have a deterrent effect on the commercial producers in developing countries that currently supply the drugs. Nevertheless, the US and the EU pursue the full endorsement of the August decision. Conversely, some developing countries hope to improve the deal on the basis of the experiences gained with its implementation.¹²

⁸ Kumar, N., "Intellectual Property Rights, Technology and Economic Development: Experiences of Asian Countries", 2002, Commission Background Paper 1b, London, Source: <http://www.iprcommission.org>

⁹ The practice of issuing a licence to use the subject matter of a patent without the authorisation of the patent holder

¹⁰ Domestic use is an ambiguous term, as it does not necessarily mean national use and could be interpreted to include regional areas, such as SADC, ECOWAS or MECRCOSUR. If this interpretation was accepted by WTO this could increase flexibilities within TRIPS and limit the need to use the August 2003 Decision

¹¹ C. Correa, "Access to drugs under TRIPS", Bridges, Year 8 No.1, ICTSD, January 2004, Geneva

¹² Bridges, "TRIPS Council addresses health, and biodiversity", Year 8 No.3, ICTSD, March 2004, Geneva. To date no developing country has used the waiver

According to the World Health Organisation, "the basic public health principle is clear: the people of a country which does not have the capacity for domestic production of a needed product should be no less protected by compulsory licensing provisions (or indeed other TRIPS safeguards), nor should they face any greater procedural hurdles, compared to people who happen to live in countries capable of producing the product."¹³

The need to find a simple, workable solution is urgent.¹⁴ In 2005, all WTO members designated as Developing

Countries which have not already done so must comply with TRIPS by introducing product patents on medicines. Thereafter, all new drugs and those for which patent applications were submitted after 1994 will be patentable, and the volume of generic exports will diminish correspondingly over time. However, it should be noted that all existing drugs produced as generics in India or elsewhere will continue to be available for export provided, of course, they are not patented in the importing country.

Patent Protection outside the WTO

Despite their declared commitment to find a solution to the problem of importing generic drugs arising from the TRIPS Agreement, industrialised countries are simultaneously insisting on even stiffer rules on patents in bilateral and regional trade agreements. These 'TRIPS Plus' clauses may undermine any progress made within the WTO.

In recent bilateral trade negotiations, US pressure led countries like Nigeria, Uganda, Morocco and Cambodia to enforce patent protection regimes for pharmaceuticals

which are more restrictive than those required under TRIPS and are thus known as TRIPS Plus. In the US negotiated Free Trade Agreement of Americas (FTAA) TRIPS Plus proposals include: limits on the circumstances in which compulsory licences can be issued; extension of patent terms beyond the 20 years required by TRIPS; and prohibition on the export of drugs produced under compulsory licence. The European Commission has already enforced a TRIPS Plus Agreement with Tunisia.¹⁵

¹³ WHO, Statement by the representative of the World Health Organisation WTO Council for TRIPS, 17 September 2002, Geneva

¹⁴ Correa has argued that the desirable features of any possible solution to the problem of compulsory licensing in countries with little or no manufacturing capacity should include: "a stable international legal framework; transparency and predictability of the applicable rules in the exporting and importing countries; simple and speedy legal procedures in the exporting and importing countries; equality of opportunities for countries in need of medicines, even for products not patented in the importing country; facilitation of a multiplicity of potential suppliers of the required medicines, both from developed and developing countries; and broad coverage in terms of health problems and the range of medicines." Correa, C, Implications of the Doha Declaration on the TRIPS Agreement and Public Health, June 2002, WHO, Geneva

¹⁵ Personal communication from David Vivas, ICTSD, Geneva, May 2004

The beginning of change?

Amongst the Group of Eight (G8) industrialised countries, Canada is the only country that has introduced legislation allowing the export of generic versions of patented drugs to countries with insufficient manufacturing capacity. Although the legislation is not entirely satisfactory, the political initiative demonstrated by Canada is a model for others to follow.¹⁶

A smaller step forward was taken in May by the US government, in response to vigorous criticisms from civil groups and HIV/AIDS activists. In a reversal of policy, the US announced that it would provide rapid approvals for generic versions of HIV/AIDS drugs. This means that US

bilateral HIV/AIDS aid programmes will be able to use cheaper generic drugs, including one pill fixed-dose combinations. Critics point out that the US insistence on using its own approval process instead of the international approval process provided by WHO is unnecessary and time consuming. Furthermore, it has yet to be seen how these generics will be priced. Three pharmaceutical companies, Bristol-Myers Squibb, Gilead Sciences and Merck & Co., have announced plans to develop a fixed-dose combination HIV medicine following the move by the US.¹⁷

Recommendations

ActionAid International calls on industrialised country governments to:

- Propose a new amendment to the TRIPS Agreement in line with the spirit of the Doha Declaration that significantly improves upon the 30th August Decision by providing a stable, transparent, predictable and simple legal framework that would facilitate the export and import of generic medicines.
- Firmly commit themselves to amend their national patent laws to allow compulsory licences to be issued and procedural bottlenecks to be removed so that generic drugs may be exported to developing and Least Developed countries

- Ensure that no rules in bilateral and regional trade agreements with developing countries hinder the export and import of generic medicines required for the treatment of HIV/AIDS and related diseases, nor undermine the multilateral progress made in the WTO on resolving the TRIPS issue.
- Increase funding for pharmaceutical research and manufacture in poor countries.

Developing and Least Developed Countries should:

- Ensure that their intellectual property protection regimes do not run counter to their public health policies and that they are consistent with and supportive of such policies.

¹⁶ Canadian HIV/AIDS legal Network, "Global access to medicines: will Canada meet the challenge?", February 2004

¹⁷ UNWIRE, "U.S. Speeds Approval Process For Generic AIDS Drugs" 17 May 2004, Global Fund Welcomes U.S. Rapid Review Of AIDS Drugs," 18 May 2004

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